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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/705,614	11/10/2003	James F. Hainfeld	16049Z	4692

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EXAMINER

HOPKINS, CHRISTINE D

ART UNIT	PAPER NUMBER
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3735

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/24/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary	Application No. 10/705,614	Applicant(s) HAINFELD ET AL.	
	Examiner Christine D. Hopkins	Art Unit 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) 26-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>19 Dec 2003</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Species I, claims 1-25 in the reply filed on December 19, 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 26-43 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim.

Priority

2. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows: If applicant desires to claim the benefit of a prior-filed application under 35 U.S.C. 120, a specific reference to the prior-filed application in compliance with 37 CFR 1.78(a) must be included in the first sentence(s) of the specification following the title or in an application data sheet. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications. Applicant's reference fails to specify the relationship.

If the instant application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition

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should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

Information Disclosure Statement

3. The information disclosure statement filed 19 December 2003 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the "Other Documents" referred to therein have not been considered.

Specification

4. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 11-13 and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 11-13 at line 2 recite the limitation "the metal cores." There is insufficient antecedent basis for this limitation in the claims. Furthermore, at line 1 of claim 25, it is unclear as to what Applicant intends to claim since the limitation recites radiation "in the form of" x-rays.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1-14, 17, 19-22 and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by Esenaliev (U.S. Patent No. 6,165,440). Esenaliev discloses the use of nanoparticles with various forms of radiation for enhancing drug delivery in tumors. Regarding claims 1-4 and 22, Esenaliev teaches a method of enhancing the effects of radiation via the administration of an anti-cancer drug to a tumor, injection of nanoparticles intravenously, and subsequent irradiation of the tumor (col. 5, lines 41-46). The tumor being irradiated may be that of brain, lung or breast tissue (col. 5, lines 50-53), in accordance with claims 5-7. Referring to claims 8 and 9, such particles injected intravenously may comprise gold (col. 10, lines 14-18).

Regarding claims 11-14, 17 and 19-21, "the metal cores" of the nanoparticles lacks antecedent basis in the claims. As such, since the nanoparticles have a surface layer of material such as an antibody coating, the metal portion of the nanoparticle is being interpreted as the "metal core." Thus, Esenaliev discloses a metal core in the range of 0.1 nm to about 7000 nm (col. 2, lines 20-28).

In accordance with claim 24, the radiation applied may be in the form of microwave, optical or RF, for example (col. 3, lines 66-67 through col. 4, lines 1-3).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Esenaliev (U.S. Patent No. 6,165,440) in view of Finkelstein (U.S. Patent No. 4,657,763). Esenaliev discloses the invention as claimed, see rejection supra; however Esenaliev fails to disclose a particular molecule, thioglucose, utilized to form the surface layer on a nanoparticle. Finkelstein teaches a method for treating a disease via administering a gold compound in association with a synergistic drug. Regarding claims 15 and 16, Finkelstein teaches the combination of gold with thioglucose such that a sufficient dosage is administered to effect inhibitory action on diseased tissue, and invoke substantial remission of a disease (col. 4, lines 32-44). Furthermore, as in the instant application, Finkelstein teaches the combination of agents to effectively treat a disease (col. 2, lines 55-68). Therefore, at the time of the invention it would have been obvious to one having ordinary skill in the art to have adsorbed a layer of thioglucose, as taught by Finkelstein, onto a gold substrate of a nanoparticle as suggested by Esenaliev et al., for forming a basis upon which an antibody may be attached that will subsequently target an antigen such as that localized within diseased tissue and furthermore provide a combination of therapies that are much more effective than when used individually.

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11. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Esenaliev (U.S. Patent No. 6,165,440) in view of Lang, Jr. et al. (U.S. Patent No. 4,515,954). Esenaliev discloses the invention as claimed, see rejection supra; however Esenaliev fails to disclose metal polyanions complexed with quaternary salts for use in radiation enhancement. Lang, Jr. et al. (hereinafter Lang) teaches a metal chelate useful for inhibiting the growth of tumors. Regarding claim 18, Lang discloses a novel metal chelate (col. 1, lines 28-45) complexed with non-toxic quaternary ammonium salts for effectively treating cancers such as leukemia (col. 2, lines 60-68 and col. 4, lines 41-47). Therefore, at the time of the invention it would have been obvious to one having ordinary skill in the art to have incorporated a metal chelate complexed with a quaternary ammonium salt, as suggested by Lang, to a nanoparticle effective in enhancing a tumor's susceptibility to radiation as taught by Esenaliev, such that the injected complex is pharmaceutically acceptable and non-toxic to a patient undergoing cancer treatment.

12. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Esenaliev (U.S. Patent No. 6,165,440) in view of Patel (U.S. Pub. No. 2005/0180917). Since Applicant fails to disclose adequate support for the claim limitations of claim 23 in Serial No. 09/363204 filed on July 29, 1999, Patel is applied as prior art under 35 U.S.C. 103(a). Esenaliev discloses the invention as claimed, see rejection supra; however Esenaliev fails to disclose a particular concentration of metal to be achieved within the tissue treated. Patel teaches the treatment of cancer at the site of, and area adjacent to, the tumor via irradiation of the diseased tissue. Regarding claim 23, Patel teaches

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nanoparticles comprising a metal, such as gold, at a concentration of about 0.1% by weight [0042]. Therefore, at the time of the invention it would have been obvious to one having ordinary skill in the art to have incorporated a metal concentration as suggested by Patel, to the composition of a nanoparticle as taught by Esenaliev, such that the susceptibility of a tumor to radiation treatment is enhanced.

13. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Esenaliev (U.S. Patent No. 6,165,440) in view of Cash, Jr. et al. (U.S. Patent No. 6,125,295). Esenaliev discloses the invention as claimed, see rejection supra; however Esenaliev fails to disclose x-ray radiation emitted in the range of "1 keV to 25,000 keV." Cash, Jr. et al. (hereinafter Cash) teaches the presence of heavy elements to enhance dosage to target tissue in radiotherapy. Regarding claim 25, Cash discloses the use of an x-ray apparatus with output in the range of 30 keV to 150 keV for treating a tumor (col. 8, lines 47-67). Therefore, at the time of the invention it would have been obvious to one having ordinary skill in the art to have subjected a tumor to x-ray radiation in an energy range proposed by Cash, in conjunction with metal nanoparticles as taught by Esenaliev, for enhancing a tumor's susceptibility to an effective amount of radiation.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine D. Hopkins whose telephone number is (571) 272-9058. The examiner can normally be reached on Monday-Friday, 7 a.m.-3:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Christine D Hopkins
Examiner
Art Unit 3735



Charles A. Marmor, II
Supervisory Patent Examiner
Art Unit 3735